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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,196	03/23/2000	ROGER JOHN DALY	1871-129	8868

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EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/509,196	DALY ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-22,24-29 and 31* is/are pending in the application.

4a) Of the above claim(s) *8-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,19-22,24-29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *30* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 09, 2003 has been entered.

Response to Amendment

2. Claims 1 and 22 have been amended and claims 23 and 30 have been cancelled as requested in the amendment of Paper No. 25, filed on February 10, 2003. Claims 1, 5-22, 24-29 and 31 are pending in the instant application.

Claims 8-18 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 1, 5-7, 19-22, 24-29 and 31 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on February 10, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Sequence compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, the sequence provided in Figures 1A-1C is not properly identified. In case this sequence is new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

Claim Rejections - 35 USC § 101

7. Claims 1, 5-7, 19-22, 24-29 and 31 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record as applied to claims 1-7 in section 9 of Paper No. 12 and further for reasons of record in sections 9 of Paper No 12 and section 6 of Paper No. 22. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the

protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

At pages 5 and 6 of the Response Applicant summarizes the statutory utility requirements and further, at page 7, traverses the rejection on the premises that the instant claimed 2.2412 protein has utility as a marker for cancerous cells. Applicant also refers to the Declaration of Hitoshi for additional evidence that 2.2412 protein has utility as a tumor marker. These arguments have been fully considered but are not deemed persuasive for the following reasons.

According to the instant specification, as filed, 2.2412 protein is "a candidate effector protein of the Grd7 family of signaling proteins" (page 1, lines 7-8, emphasis added). It is further stated that "Grb7 family proteins exhibit differential expression in certain human cancers (particularly breast and prostate cancer) and may therefore be involved in tumour progression" (page 5, lines 13-15, emphasis added). Thus, at the time of filing, the instant specification disclosed the following information: novel interacting protein 2.2412 was isolated because it interacted with Grb14 protein within yeast two hybrid system; because this protein binds Grb14, it is asserted to be associated ("a candidate effector") with Grb7 family of proteins; it is known from the literature that Grb7 proteins can be differentially expressed in certain cancers. It is further asserted in the instant specification that "[d]etection of the protein encoded by the cDNA 2.2412 in a sample should provide a useful tumor marker and prognostic indicator for [these] cancers" (page 5, lines 13-19 of the instant specification).

The assertion that a novel 2.2412 protein encoded by the claimed polynucleotide is a candidate effector protein for the Grb7 proteins, which maybe associated with cancer, does not

make the instant DNA or encoded protein diagnostic of cancer. The instant specification fails to provide any evidence or sound scientific reasoning to allow a conclusion that the instant 2.2412 protein encoded by the claimed polynucleotides is associated with any cancers, including prostate or breast cancer. A specification can meet the legal requirements of utility and enablement for a new polynucleotide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new polynucleotide, or a well-established utility for the claimed polynucleotide would be *prima facie* obvious to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed polynucleotide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed polynucleotide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern here. The instant specification discloses that the claimed nucleic acid encodes a protein that binds Grb7 and Grb14 proteins *in vitro* and hypothesizes that the detection of claimed polynucleotides can be used for the diagnosis of cancer because Grb7 proteins are reported to be differentially expressed in certain cancers. However, there is no disclosure that the claimed polynucleotides are expressed at altered levels or forms in any specific, diseased tissue or otherwise associated with any particular cancer, as implied by the instant specification. Therefore, one skilled in the art using the instant disclosure, as originally filed, would clearly not be able to diagnose any cancer due to the lack of critical information regarding specific association of 2.2412 and a particular type of cancer.

Furthermore, it is clearly stated in the instant specification that "the new sequence is expressed in all tissues except kidney cells" (page 10, second paragraph). Based on this disclosure, one skilled in the art would reasonably conclude that the novel polypeptide 2.2412 cannot possibly be a specific marker for any cancer cells due to the general pattern of its tissue distribution. Applicant argues that because Grb7 and Grb14 are differentially expressed in breast cancer, "one would reasonably expect that expression of 2.2412 would also be differentially expressed, and such expression would be different between normal and cancerous cells of the same tissue origin" (page 8, second paragraph of the Response). This argument has been fully considered but is not deemed to be persuasive because the instant specification, as filed does not provide any information regarding a specific level of expression of 2.2412 protein in normal versus cancerous tissue for any type of cancer. 35 USC § 101 clearly states that the invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. The fact that Applicant submits that some experimentation to provide evidence of differential expression of 2.2412 protein in normal and cancerous cells may be required to practice the claimed invention simply confirms that the instant invention was not completed as filed, and, therefore, clearly lacks utility in currently available form.

The Declaration of Hitoshi under 37 CFR 1.132 filed on February 10, 2003 is insufficient to overcome the rejection of the instant claims as set forth in the last Office action because: the Declaration presents additional information regarding expression of 2.2412 protein using Taqman assay. Specifically, additional data show that 2.2412 was expressed at significantly higher levels in two types of lung cancer and in three types of breast cancer. However, as it was

fully explained in the instant office action and earlier in the appropriate sections of Papers No. 10, 12 and 22, the instant specification, as filed, fails to provide any information regarding using novel 2.2412 sequences as a specific marker for breast and lung cancer. General suggestion that 2.2412 protein can be used as a tumor marker does not stand for assertion of specific substantial and credible utility. Moreover, there was no evidence of record in the instant specification, which specifically associates the instant DNA or encoded protein with any human cancers. Applicant's own statement confirms that the novel 2.2412 is broadly expressed in all normal tissues, and, consequently, cannot be specific for any tissue except for normal kidney cells, see the explanation earlier. Any further subsequent characterization of the claimed DNA and encoded protein, which can and will lead to the discovery of a specific and substantial credible utility is considered to part of the act of invention. Unless credible specific and substantial utility of the claimed compound is disclosed in the specification as filed, Applicant's claimed invention is incomplete. "[A] patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion". *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966).

Therefore, because the instant specification does not disclose a specific, substantial and credible "real world" use for the claimed novel polynucleotide sequences encoding 2.2412 protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

8. Claims 1, 5-7, 19-22, 24-29 and 31 also stand rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-7 in section 10 of Paper No. 12 and further for reasons of record in section 7 of Paper No. 22.

9. Claims 1, 5-7, 20, 22, 24-26 and 28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 1-3 in section 12 of Paper No. 12 and further for reasons of record in section 8 of paper No. 22.

Applicant argues that "the specification provides both structural and functional information about the claimed polynucleotide" (page 10, last two paragraphs of the Response) and further, that the claims, as amended, now recite 95% sequence identity to SEQ ID NO: 1 or 2. These arguments have been considered but are not persuasive because claims 1, 5-7, 20, 22, 24-26 and 28 encompass polynucleotides which have 95% identity a nucleic acid having SEQ ID NO:1 or which encode an amino acid sequence having 95% identity to a protein of SEQ ID NO: 2, and the instant specification fails to describe the entire genus of polynucleotides which are encompassed by these claims. First, the claims are not limited to a polynucleotide with a specific nucleic acid sequence. The claims only require the polynucleotide to share some degree of structural similarity to the isolated polynucleotide of SEQ ID NO: 1 and to have the activities possessed by the isolated protein encoded by the claimed polynucleotides. Therefore, there is a

lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Furthermore, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polynucleotide of SEQ ID NO: 1 encoding a protein of SEQ ID NO: 2. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus of the polynucleotides. Therefore, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's argument with respect to other US Patents having claims reciting 95% sequence identity (page 11 of the Response) is not persuasive because it is well settled that the prosecution of one patent application does not affect the prosecution of an unrelated application. *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976) (holding that "[I]t is immaterial in *ex parte* prosecution whether the same or similar claims have been allowed to others").

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-7939. Official papers should NOT be faxed to (703) 308-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.